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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,083

04/14/2004

Ronald J. Lebel

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23392 7590 10/10/2006

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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,083

Applicant(s)

LEBEL ET AL.

Examiner

Mark W. Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-33 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18-33 and 40-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8-16-04,3-23-05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell USPN 4,731,051. Fischell teaches a method of conserving power in an implantable drug delivery pump medical device. The examiner considers the transmitter receiver unit 36 to be a processor for processing transmitted signals, and the controller 35 to be a MD functional unit. The method is taught in connection with figure 9, "Idle state", and described in column 12 starting at lines 33. The implanted device has an idle state, which is used for shipping etc. and in which energy is conserved by suppressing clock pulses to the controller. The idle state can be entered at any time to conserve energy thereby disabling clock pulses to the controller. Clock pulsing to the controller can be re-enabled by sending a command to the medical device to enter a standby state. The controller module interfaces with a pump module as seen in figure 2.

In a second interpretation of the claims the examiner considers the medical device to include a processor in external programmer 12 and functional unit module unit

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13 which has clock enablement and disablement features as described above. The examiner considers the entire functional module to be a telemetry module.

Claims 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Thompson USPN 6,167,203. Thompson shows a medical device for sensing ecg signals in figure 9 having a processor 314 and a clock source 338. In the description accompanying figure 3, a clock source may provide clock signals to at different frequencies to various circuits which the examiner considers to modules. The clocking element 34 is described as a low frequency clock with an on/off high frequency clock output. (column 6 lines 50-65), The circuits 32 may include discrete function circuits such as a telemetry circuit which the examiner considers to be a functional module. The clocking to the telemetry circuit, which is disclosed as one of the high frequency clock circuits may thus have its clocking pulses enabled and disabled as needed by the clock control element. See column 11 lines 1-14, and column 17 lines 30-48 in describing the implementation of the RF transmitter/receiver element when needed during specific time periods.

Claims 18-20, 23-24, 29, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Stanton et al. USPN 6,249,703. Stanton teaches a communication device that is designed to program implantable medical devices. The communication device has a CD telemetry system 52m 54 26, a CD processor 50, and warning devices including a beeper and a led to indicate battery status. The device is to be used with a host of implantable devices as noted in the Background section including stimulation

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devices. These programmable devices are known to have processors and telemetry units. The telemetry system is operated by downlink/uplink first portion that is incorporated inside the MD processor and a second portion including transmitter/receiver circuits positioned external of the first portion. In addition, functional modules LED system and beeper system are provided. LED system indicates when the battery is considered to be low by flashing, the threshold would be determined by the person setting the device threshold for the amount of time left to allow the patient to address the problem. Stanton indicates that the battery voltage is continually monitored by the MD.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton et al. USPN 6,249,703 in view of Ogden USPN 6,070,103. Applicant differs from Stanton et al in reciting the MD has a battery that is rechargeable or non-rechargeable. Both types of power sources are notoriously well known inclusions in IMDs as evidenced by Ogden.

Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton et al. USPN 6,249,703. Applicant differs in reciting time periods remaining to ensure adequate power not specified by Stanton et al. But to have chosen the threshold

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voltage corresponding to a month or less of operation time to indicate the low voltage signal would have been an obvious time frame to give the patient warning for adjustment.

Claims 21-22 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton et al. USPN 6,249,703 in view of Renirie et al USPN 5,369,364. Applicant differs in testing voltages against difference impedances to indicate battery status. Renirie et al demonstrate such a test for an IMD. To have used the Renirie IMD with the Stanton et al programmer for their disclosed advantages would have been an obvious choice.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272 -6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWB

September 21, 2006


MARK BOCKELMAN
PRIMARY EXAMINER